

PATENT COOPERATION TREATY

TRANSLATION

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To:

Date of mailing
(day/month/year)

Applicant's or agent's file reference

FP05-0010-00

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/JP2005/001348

International filing date (day/month/year)

31.01.2005

Priority date (day/month/year)

30.01.2004

International Patent Classification (IPC) or both national classification and IPC

Applicant

HISAMITSU PHARMACEUTICAL CO., INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/JP

Authorized officer

Facsimile No.

Telephone No.

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Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
- a. type of material
- ☐ a sequence listing
- ☐ table(s) related to the sequence listing
- b. format of material
- ☐ in written format
- ☐ in computer readable form
- c. time of filing/furnishing
- ☐ contained in the international application as filed.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
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International application No.

PCT/JP2005/001348

Box No. V	Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement		
1. Statement			
Novelty (N)	Claims	1-6	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	1-6	NO
Industrial applicability (IA)	Claims	1-6	YES
	Claims		NO
2. Citations and explanations:			
<p>Document 1: JP, 7-132946, A (Kabushiki Kaisha Seisan Nihonsha), 23 May, 1995 (23.05.95), paragraph [0013]</p> <p>Document 2: JP, 9-511987, A (Noven Pharmaceuticals, Inc.), 2 December, 1997 (02.12.97), page 13, line 28 to page 16, line 2, page 16 to line 26 to page 32 to line 1 & WO, 1995-018603, A1, Description, page 12, line 5 to page 14, line 21, page 15, line 18 to page 29, line 3 & EP, 0737066, B1, paragraph [0039]-[0047], [0052]-[0053]</p> <p>Document 3: Microfilm of the specification and drawings annexed to the request of Japanese Utility Model Application No. 156951/1984 (Laid-open No. 73547/1986), (Toppan Printing Co., Ltd.), 19 May, 1986 (08.05.92), Description, page 6, line 13 to page 9, line 4</p> <p>Document 4: JP, 5-305108 (Nitto Denko Corp.), 19 November, 1993 (19.11.93), paragraphs [0010], [0017]</p> <p>The subject matter of claim 1 does not appear to involve an inventive step in view of documents 1, 2 and 3 cited in the ISR. Document 1 describes about a packing bag having an inner surface made of polyacrylonitrile, which comes in contact with a dressing accommodated at an inner part. A person skilled in the art could have easily employed the point of including bisoprolol to an adhesive layer described in document 2, and the point of attaching a releasing film to an adhesive layer described in document 3, to the dressing described in document 1.</p> <p>The subject matter of claim 2 does not appear to involve an inventive step in view of documents 1-3 and document 4 cited in the ISR. A person skilled in the art could have easily used the adhesive selected from among a block copolymer adhesive containing a styrene system block copolymer, an acryl system adhesive containing a copolymer including as a monomer unit the (meth) acrylic ether described in documents 2 and 4, to be used as an adhesive having an adhesive layer in the dressing of document 1.</p> <p>The subject matter of claim 3 does not appear to involve an inventive step in view of documents 1-4. Document 1 describes about the packing bag comprising multilayer films, and an innermost surface of the multilayer films is made of polyacrylonitrile.</p> <p>The subject matter of claim 4 does not appear to involve an inventive step in view of documents 1-4. Document 1 describes the point of preparing an outermost surface multilayer films made of polyethylene terephthalate.</p> <p>The subject matter of claim 5 does not appear to involve an inventive step in view of documents 1-4. Document 1 describes about preparing the inner surface multilayer film and the outer surface multilayer film, and describes the point of providing an aluminum layer in between these multilayer</p>			

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Box No. V

Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement

films.

The subject matter of claim 6 does not appear to involve an inventive step in view of documents 1-2. Document 1 describes a drug shift control method by using the packing bag having the inner surface made of polyacrylonitrile, which comes in contact with the dressing accommodated at the inner part. A person skilled in the art could have easily employed the point of including bisoprolol to the adhesive layer described in document 2, to the dressing described in document 1.